Exhibit 1.2

VERIFICATION OF TRANSLATION

Re : Japanese Patent Application No. 2001-253740

I, Sonoko TSUKIYAMA, of c/o Hosoda International Patent Office, OMM Building 5th Floor, P.O. Box 26, 1-7-31 Otemae, Chuo-ku, Osaka 540-6591, JAPAN, hereby declare that I am the translator of the documents attached and certify that the following is a true translation of the best of my knowledge and belief.

Dated this 21st day of February, 2007

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(54) [Title of the Invention] Composition for Treating Mood Disorders

(57) [Abstract] (corrected version)

[Problems] To provide a composition for treating mood disorders, wherein the composition is capable of exhibiting a significant effect in the suppression of mood disorders with hardly any side effects.

[Solving Means] A composition containing theanine, an amino acid abundantly contained in green tea. There are various processes for preparing theanine, such as a process of extracting theanine from tea-leaves; an organic synthesis reaction; a process of enhancing proliferation of cultured cells of tea-leaves, and the like, and any of them can be employed. The tea-leaves include those of green tea, oolong tea, black tea, and the like.

[Claims]

[Claim 1] A composition for treating mood disorders, characterized in that the composition comprises theanine.

[Claim 2] A food or medicament comprising a composition for treating mood disorders, characterized in that the composition comprises theanine as defined in claim 1.

[Claim 3] A method for producing a food or medicament comprising a composition for treating mood disorders, characterized in that the composition comprises theanine as defined in claim 1.

[Detailed Description of the Invention]

[0001]

[Technical Field to Which the Invention Pertains] The present invention relates to a composition for treating mood disorders, characterized in that the composition comprises theanine, and to a food or medicament comprising the composition, and further to a method for producing the food or medicament.

[0002]

[Prior Art] Conventionally, mental disorders called "manic-depressive disorders" have been classified into disorders showing both a manic state and a depressed state (dipolar disorders) and disorders showing only a depressed state (monopolar disorders). However, manic-depressive disorders are now called "mood disorders" as a generic name referring to these two kinds of disorders. According to the results of epidemiological questionnaires conducted recently in Western advanced countries, the proportion of the number of individuals suffering from mood disorders especially suffering from depression or showing a depressed state to the total population (morbidity of individuals suffering from depression or showing a depressed state) has been certainly increasing. Especially with the coming of aging society, it is said that the morbidity exceeds 10%. Although the causations for mood disorders have not yet been clarified, a presumption includes "the deficiency of function of a monoamine in the brain." Based on this presumption, a medicament acting on the function of the

monoamine in the brain has been used for the treatment of depression in mood disorders.

[0003] The medicament exhibiting an antidepressive action includes an MAO inhibitor. MAO is an abbreviation standing for a monoamine oxidase, which is an enzyme acting to oxidize a chemical transmitter such as a monoamine including norepinephrine, serotonin or dopamine, thereby inactivating the chemical transmitter. The MAO inhibitor includes iproniazid, phenyprazine, phenelzine, nialamide, isocarboxyazid, safrazine and the like. However, there are many limitations upon its use because of problems of severe side effects such as hepatic disorders, the risk of the combined use of the inhibitor with a tricyclic antidepressant, limitations in the intake of high tyramine-content food, or the like. Therefore, all MAO inhibitors are discontinued to be sold at present.

[0004] The tricyclic antidepressant is often used as an antidepressant. Representative medicaments include imipramine hydrochloride (trade name: Tofranil), clomipramine hydrochloride (trade name: Anafranil), amitriptyline hydrochloride (trade name: Tryptanol), desipramine hydrochloride (trade name: Pertofrane), amoxapine (trade name: Amoxan), lofepramine hydrochloride (trade name: Amplit) and the like.

[0005] The action mechanism of the tricyclic antidepressant is an action of suppressing reuptake of a monoamine released from a nerve ending. A medicament having a strong suppressive effect on reuptake of a monoamine norepinephrine includes desipramine hydrochloride and amoxapine, and a medicament having a strong suppressive effect on reuptake of serotonin includes clomiprane hydrochloride. It is understood that amitriptyline hydrochloride and imipramine hydrochloride act moderately for suppressing reuptake of norepinephrine and serotonin.

[0006] Further, a tetracyclic antidepressant has been developed as a medicament having smaller side effects than those of the tricyclic antidepressant. Representative medicaments include maprotiline hydrochloride (trade name: Ludiomil), mianserin hydrochloride (trade name: Tetramide), setiptiline maleate

(trade name: Tecipul), and the like. The tetracyclic antidepressant mainly has an effect of accelerating release of a monoamine from a nerve ending. It is understood that the tetracyclic antidepressant has an effect of blocking α-2 receptors, thereby increasing the amount of a monoamine released.

[0007] The tricyclic and tetracyclic antidepressants have been known to have side effects. One of the side effects is an anti-choline symptom. It has been known that the tricyclic and tetracyclic therapeutic agents antagonize to an action of acetylcholine as a chemical transmitter in the parasympathetic nervous system. Concrete symptoms of the side effects include an increase in ocular tension by means of light scattering or the like, dry mouth, suppression of digestive tracts such as constipation, difficulty in urination, and the like. Also, besides the anti-choline symptom, drowsiness is induced by their suppressive action on the central nervous system, and further orthostatic hypotension has been also known as a side effect on the circulatory system. The side effect of the tetracyclic antidepressant is smaller than that of the tricyclic antidepressant, but its antidepressive effect is said to be smaller.

[0008] There are therapeutic agents called SSRIs (selective serotonin reuptake inhibitors) which are antidepressants having smaller side effects than those of the tricyclic and tetracyclic antidepressants. SSRIs have the feature of high selectivity for reuptake of serotonin among monoamines released from a nerve ending. A representative medicament is fluvoxamine maleate (trade names: Depromel and Luvox). Its side effects include digestive diseases such as nausea and emesis at an initial stage of administration, with the side effects being smaller than those of the tricyclic and tetracyclic antidepressants. In addition, its combined use with the MAO inhibitor, an anti-allergic agent such as terfenadine (trade name: Triludan) or astemizole (trade name: Hismanal), or a digestive movement improver such as cisapride (trade names: Acenalin and Risamol) has been known to be contraindicative.

[0009] In addition, a common feature of the antidepressants includes a delayed exhibition of their effects. It has been known that the antidepressants

are highly fat-soluble and have a high binding ratio to plasma proteins, so that there are immediate effectiveness and delayed exhibition of the effects. Therefore, it is deduced that the effect is exhibited by some influences caused by continuous stimulation. Also, it has been reported that the number of receptors is decreased by continuous stimulation with monoamines released.

[0010]

[Problems to Be Solved by the Invention] The present invention provides a composition for treating mood disorders which solves the above-mentioned problems. More specifically, the present invention provides a composition for treating mood disorders with hardly any side effects.

[0011]

[Means to Solve the Problems] As a result of intensive studies on substances effective in the treatment of mood disorders, the present inventors have found that theanine, an amino acid abundantly contained in green tea, is effective for solving the above-mentioned problems. The present invention has been accomplished thereby. The above-mentioned effects of theanine is a novel effect found for the first time by the present inventors. The present invention will be described in detail hereinbelow.

[0012]

[Modes for Carrying out the Invention] The term "mood disorders" as used herein refers to symptoms given in International Classification of Diseases, 10th edition, issued by World Health Organization (WHO). According to the classification, the mood disorders are described as symptoms showing changes in moods such as depression and elation. The fundamental disorder in the mood disorders is defined as follows: "A change in moods or emotions, which is usually changed to depression or to elation. Generally, this change in moods is accompanied by a change in whole activity, and most of other symptoms occur secondarily from this change or can be easily understood from the relationship therewith." In other words, as the mood disorders, there are two symptoms: disorders showing both a manic state and a depressed state (dipolar disorders)

and disorders showing only a depressed state (monopolar disorders). Theanine of the present invention serves to ameliorate the depressed state of the mood disorders.

[0013] The symptoms observed in patients in a depressed state include depressed moods, loss of interest and pleasure, an easily increased fatigue and a decreased activity due to a loss in vitality, feel of severe fatigue after trying hard, a diminished concentration and attentiveness, lowered self-evaluation and self-confidence, feelings of guilt and sense of worthlessness, hopeless and pessimistic views for future, ideas and gestures of self-injury and suicide, sleep disorders, loss of appetite and the like. In order to establish the diagnosis according to the diagnostic guidelines ICD-10, at least two items selected from depressed moods, loss of interest and pleasure, and easily increased fatigue, and at least two items selected from diminished concentration and attentiveness, lowered self-evaluation and self-confidence, feelings of guilt and sense of worthlessness, hopeless and pessimistic view for future, ideas and gestures of self-injury or suicide, sleep disorder, and loss of appetite must persist at least 2 weeks.

[0014] A depressed state is frequently found in women. The depressed moods are also found before and during the menstruation, but such depressive symptoms accompanying the menstruation cycle are excluded from the above-mentioned diagnostic guidelines. Theanine used in the present invention is a glutamic acid derivative contained in tea-leaves, which is the main component of tastiness (*umami*) of tea. It is used as a food additive for giving *umami* (tastiness). Processes for preparing theanine used in the present invention are, but not limited to, a process of extracting theanine from tea-leaves; a process for obtaining theanine by an organic synthesis reaction [*Chem. Pharm. Bull.*, **19(7)**, 1301-1307 (1971)]; a process of treating a mixture of glutamine and ethylamine with glutaminase to give theanine (Japanese Examined Patent Publication No. Hei 7-55154); a process comprising culturing cultured cells of tea in a medium containing ethylamine, thereby enhancing proliferation of the cultured cells

while increasing the cumulative amount of theanine in the cultured cells (Japanese Patent Laid-Open No. Hei 5-123166); modification processes in which ethylamine is substituted by an ethylamine derivative such as ethylamine hydrochloride in the processes using cultured cells disclosed in Japanese Examined Patent Publication No. Hei 7-55154 or Japanese Patent Laid-Open No. Hei 5-123166; and the like, and any of the processes may be used. The term "tea-leaves" as referred to herein includes those from green tea, oolong tea, black tea, and the like. Theanine obtained by the process as mentioned above can be used as any of L-form, D-form and DL-form. Among them, the L-form is preferred in the present invention, because the L-form is also approved as a food additive, and is economically utilizable.

[0015] The mechanism for the antidepressive effect of theanine has not been elucidated. In an animal test using rats, it has been known that theanine passes through the brain barrier by means of oral administration. As actions of theanine, it has been deduced that an increase in the dopamine level in the brain is recognized by directly administering theanine into the brain, or that some sorts of actions are brought about in the brain by influencing the pharmakinetics of serotonin or norepinephrine by the administration of theanine.

[0016] The theanine used in the present invention has high safety. For instance, in an acute toxic test using a mouse, there are no cases of death with an oral administration at 5 g/kg weight, and there are found no abnormalities in the general states, body weight and the like. Also, especially L-theanine is known as a main component of *umami* (tastiness) of the green tea, and is also used as a food additive giving *umami*, without the limitation of its added amount under the regulation for food hygiene. Moreover, contrary to the conventional drugs, since there is no side effect by theanine at all, the treatment of the mood disorders can be safely and effectively achieved according to the composition of the present invention.

[0017] In addition, theanine used in the present invention may be any of the forms of purified products, crudely purified products, extracts, and the like. The

composition for treating mood disorders, which is an inventive product, refers to theanine as it is, or alternatively to foods and medicaments, wherein each contains theanine, such as dry foods, supplements, liquid foods such as refreshing beverages, mineral waters, luxury beverages, alcoholic beverages, tablets, capsules, powders, granules, and health-care drinks.

[0018] The beverage as listed herein includes, but is not particularly limited to, teas such as green tea, oolong tea, black tea and herb tea, fruit juice concentrates, reconstituted juice concentrates, fresh juices, mixed fruit juices, fruit grain-containing fruit juice, fruit juice-containing beverages, mixed fruit/vegetable juice, vegetable juice, carbonated beverages, soft drinks, milk beverage, Japanese *sake*, beer, wine, cocktails, *shochu*, whiskey, and the like.

[0019] Also, in the composition for treating mood disorders of the present invention, crude medicines, herbs, amino acids, vitamins, and other materials and raw materials which are acceptable in foods can also be used together. The above crude medicine as used herein includes, but is not particularly limited to, *Common valerian*, *Angelica acutiloba*, *Paeonia lactiflora*, peony, *Panax ginseng* and the like, which are effective for maintaining hormonal balance in women.

[0020] The herbs include, but are not particularly limited to, anise, carrot seed, clove, coriander, cypress, cinnamon, juniper, ginger, sweet orange, pine needle, basil, patchouli, bitter orange, fennel, black pepper, bay, peppermint, bergamot, mandarin, myrrh, lemongrass, rosemary, grapefruit, cedarwood, citronella, sage, thyme, tea tree, violet leaf, vanilla, hyssop, eucalyptus, lime, lemon, ylang-ylang, cardamon, clary sage, jasmine, geranium, chamomile, Bulgarian rose, rose, olibanum, lavender, chamomile, geranium, sandalwood neroli, verbena, petigrain, vetiver, majoram, lemon balm (*Melissa officinalis*), rosewood, *Hypericum*, St. John's wort, and kawakawa, with preference given to peppermint, bergamot, ylang-ylang, geranium, chamomile, lavender, St. John's wort, and kawakawa, which have sedative and relaxation effects. The forms of these herbs include, but are not particularly limited to, extract, essential oil, herb tea, and the like.

[0021] The amino acid used includes, but is also not particularly limited to, for example, glutamine, glutamic acid, inosinic acid, alanine, arginine, aspartic acid, threonine, serine, γ-aminobutyric acid, taurine, thiotaurine, hypotaurine and the like.

[0022] The vitamin used includes vitamin A, vitamin B_1, vitamin B_2, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin E, vitamin K, folic acid, nicotinic acid, lipoic acid, pantothenic acid, biotin, ubiquinone, prostaglandin, and the like, as well as derivatives of these vitamins, but is not limited thereto.

[0023] The mineral used includes calcium, iron, magnesium, copper, zinc, selenium, potassium, and the like, but is not limited thereto.

[0024] In addition, there can be used aloe, royal jelly, melatonin, placenta, propolis, isoflavone, soybean lecithin, egg yolk lecithin, egg yolk oil, chondroitin, cacao mass, collagen, vinegar, cholera, spirulina, ginkgo leaves, green tea, tochu tea (*Eucommia ulmoides*), Chinese wolfberry tea, oolong tea, mulberry leaf, *Rubus suavissimus* (tencha), banaba tea, unsaturated fatty acids, saccharides such as oligosaccharides, bacteria such as bifidobacteria and red koji, mushrooms such as agaricus (*Agaricus blazei*), *Agaricus blazei Murrill*, reisi (*ganoderma*) and *Grifloa frondosa*, fruits such as blueberry, prune, grape, olive, Japanese apricot and citruses, seeds such as peanut, almond, sesame and pepper, vegetables such as green pepper, chili, Welsh onion, pumpkin, gourd, carrot, burdock, jute leaf (*Corchorus capsularis*), garlic, perilla, Japanese horseradish (*wasabi*), tomato, (pickled) shallot, leaf vegetables, tubers and beans, seaweeds such as wakame, fishes and shells, meat, poultry and whale meat, cereals and the like. Further, extracts, dried products, crudely purified products, purified products, processed products, fermentation products and the like of the above-mentioned components can be also used.

[0025] The process for preparing the composition for treating mood disorders of the present invention is not particularly limited, and there can be applied general processes of producing a food or medicament, such as a process of mixing theanine with other starting materials in a powdery form, a process of

dissolving theanine and other starting materials in a solvent to give a mixed solution, a process of lyophilizing the mixed solution, a process of spray-drying the mixed solution, and the like. The content of the theanine in the composition of the present invention is not particularly limited, and it is preferable that the content of the theanine is 0.00025% or more, taken into consideration together with the effective dose of the theanine.

[0026] The effective dose of theanine in the present invention is from 0.2 mg/kg body weight to 200 mg/kg body weight, preferably from 0.5 mg/kg body weight to 50 mg/kg body weight per day. However, since there are individual differences in the kind and extent of symptoms listed above, the range of the present invention is not limited to those given above.

[0027] The form of the manufactured article of the present invention may be, but is not particularly limited to, one that is orally administrable such as solution, suspension, powder, or molded solid product. More specifically, there may be exemplified pasty products, processed soybean products, seasonings, mousses, jelly, frozen confectionaries, candies, chocolates, chewing gums, crackers, cakes, breads, soups, coffees, cocoas, teas, green tea, juices, milk beverages, dairy products, liquors, tablets, capsules, medicaments, and the like. The present invention will be described by the following examples, without intending to limit the present invention thereto. The present invention will be described hereinbelow by means of the following Examples and Test Examples, without intending to limit the present invention to these Examples and Test Examples.

[0028]

[Examples] Example 1 Preparation of Theanine by Enzymatic Method

The amount 21.9 g of glutamine and 28.5 g of ethylamine hydrochloride were allowed to react at 30°C for 22 hours in 0.5 L of 0.05 M borate buffer (pH 9.5) in the presence of 0.3 U glutaminase (manufactured by Amano Enzyme Inc.). Thereafter, the reaction mixture was subjected to column chromatography using Dowex 50 × 8 column and Dowex 1 × 2 column (both manufactured by Muromachi Kagaku Kogyo K.K.), and thereafter the resulting product was

treated with ethanol, thereby isolating a desired product from the reaction mixture.

[0029] The confirmation of the obtained substance as L-theanine was carried out by subjecting the isolated substance to amino acid analyzer and paper chromatography, and showing that the isolated substance exhibits the same behaviors as the standard substance. Moreover, when the isolated substance was subjected to hydrolysis treatment with hydrochloric acid or glutaminase, glutamic acid and ethylamine were generated at a ratio of 1:1. As described above, since the isolated substance was hydrolyzed by glutaminase, it was shown that ethylamine was bonded at the γ-position of glutamic acid. In addition, it was also confirmed by using the glutamic acid dehydrogenase that glutamic acid generated by hydrolysis had an L-form. By the above procedure, 8.5 g of L-theanine was obtained.

[0030] Example 2 Extraction of L-Theanine from Tea Leaves

Ten kilograms of tea leaves (*Camellia sinensis L.*) were subjected to extraction with boiling water. The resulting extract was then applied to a cationic exchange resin ("Dowex HCR W-2," manufactured by Muromachi Kagaku Kogyo K.K.), and the component adsorbed to the resin was eluted with 1 N NaOH. The eluted fraction was applied to an activated carbon ("Taiko Kasseitan SG" manufactured by Futamura Kagaku Kogyo K.K.), and eluted with 15% ethanol. The resulting eluted fraction was concentrated with an RO membrane ("NTR 729 HF" manufactured by NITTO DENKO CORPORATION). Thereafter, the concentrate was purified by column chromatography. Furthermore, the purified product was recrystallized, to give 24.8 g of L-theanine. Here, in the preparation of each composition described hereinbelow, L-theanine [trade name: Suntheanine, manufactured by Taiyo Kagaku Co., Ltd.] was used.

[0031] Example 3 Preparation of Theanine-Formulated Tablet

As one example of the theanine-formulated composition for treating mood disorders, a theanine-formulated tablet was prepared by mixing the raw

materials given below, and tableting the resulting mixture.

Frosted Sugar	71.67% by weight	(0.5375 g)
Trehalose	10% by weight	(0.075 g)
L-Theanine	13.33% by weight	(0.1 g)
Sucrose Fatty Acid Ester	1% by weight	(0.0075 g)
Flavor (Lemon Flavor)	4% by weight	(0.03 g)
Total	100% by weight	(0.75 g)

Specifically, each of the raw materials was mixed in accordance with the above composition, and the mixture was granulated to give a tablet of 0.75 g.

[0032] Comparative Example 1 Preparation of Control Tablet

A control tablet was prepared by mixing the raw materials given below, and tableting the resulting mixture.

Frosted Sugar	85% by weight	(0.6375 g)
Trehalose	10% by weight	(0.075 g)
Sucrose Fatty Acid Ester	1% by weight	(0.0075 g)
Flavor (Lemon Flavor)	4% by weight	(0.03 g)
Total	100% by weight	(0.75 g)

Specifically, each of the raw materials was mixed in accordance with the above composition, and the mixture was granulated to give a tablet of 0.75 g.

[0033] Example 4 Preparation of Theanine-Formulated Candy

As one example of the theanine-formulated composition for treating mood disorders, a theanine-formulated candy was prepared using the following raw materials.

Granulated Sugar	64 kg
Malt Syrup	23 kg
L-Theanine	10 kg
Flavor (Lemon Flavor)	0.05 kg
50% Tartaric Acid	1 kg
Water	30 kg

The granulated sugar was dissolved in 20 kg of water with heating to 110°C. Ten kilograms of the remaining water in which L-theanine was dissolved, and malt syrup were added thereto, and the temperature was raised to 145°C. After heating was stopped, 50% tartaric acid were added thereto and mixed. The mixture was cooled to 75° to 80°C, and formed with a molding roller, to give a theanine-formulated candy. The content of L-theanine in the candy was determined. As a result, its content was 89.6 mg/g per drop of 1.2 g.

[0034] Example 5 Preparation of Theanine-Formulated Blueberry Beverage

As one example of the theanine-formulated composition for treating mood disorders, a theanine-formulated blueberry beverage was prepared using the following raw materials.

Fructose Sucrose Solution	12 kg
Blueberry Concentrate Juice	1 kg
1/5 Transparent Lemon Juice	0.4 kg
Sodium Citrate	0.05 kg
50% Sodium Citrate (Crystals)	for pH adjustment
L-Theanine	0.1 kg
Flavor (Blueberry Flavor)	0.05 kg
Water	Proper amount
Total	100 kg

Fructose glucose solution, blueberry concentrate juice, 1/5 transparent lemon juice, sodium citrate and L-theanine were added to water to dissolve the components with stirring. The solution was adjusted to pH 3.1 with 50% sodium citrate (crystals) and heated to 95°C, and the flavor was added thereto, and the mixture was filled into a 100-ml can and then cooled to produce a theanine-formulated blueberry beverage. The L-theanine in the blueberry beverage was quantified. As a result, the content was 98.3 mg/100 ml.

[0035] Example 6 Preparation of Theanine-Formulated Grapefruit Beverage

As one example of the theanine-formulated composition for treating mood disorders, a theanine-formulated grapefruit beverage was prepared using the following raw materials.

Fructose Sucrose Solution	6 kg
L-Theanine	0.1 kg
Ferric Pyrophosphate	0.06 kg
Placenta Extract	0.01 kg
100% Grapefruit Juice	30 kg
Sodium Citrate	for pH adjustment
Flavor (Grapefruit Flavor)	0.05 kg
Water	Proper amount
Total	100 kg

Fructose sucrose solution, L-theanine, ferric pyrophosphate, placenta extract and 100% grapefruit juice were added to water with stirring to dissolve the components. The pH of the resulting solution was adjusted to 3.1 by using sodium citrate. After the temperature was raised to 95°C, the flavor was added thereto. The resulting solution was filled in an amount of 100 ml each, and then cooled to produce a theanine-formulated grapefruit beverage. The L-theanine in the grapefruit beverage was quantified. As a result, its content was 96.4 mg/100 ml.

[0036] Test Example 1 Test for Therapeutic Effects on Mood Disorders

The therapeutic effects on mood disorders were examined for a group of 24 normofolatemic patients. In diagnosis, the patients were assessed to be mild to severe according to the diagnostic criteria of DMS III R. The test was conducted in double blind, and the test period was 3 weeks. The 24 patients were divided into two even groups. One group was administered with the theanine-formulated tablet prepared in Example 3, and the other group was administered with the control tablet prepared in Comparative Example 1. Each patient was administered every day with one tablet twice a day, at 10 am and 4 pm. The therapeutic effects were assessed according to the Hamilton scale

consisting of 31 items regarding the assessment for depression. The assessment was made before the intake of each tablet and on Day 7, Day 14 and Day 21 from the intake.

[0037] An average score of the Hamilton scale for each of the group of the patients administered with the theanine-formulated tablet of Example 3 and the group administered with the control tablet of Comparative Example 1 is shown in Figure 1. The average score of the Hamilton scale was significantly decreased from "24" before the intake to "15" after 3 weeks of the intake in the group administered with the theanine-formulated tablet of Example 3 ($p < 0.01$), while a reduction in the score in the group administered with the control tablet of Comparative Example 1 was hardly recognized. In the theanine-formulated tablet of Example 3, it was suggested that the therapeutic effects were observed as early as after 1 week from the intake. In addition, some sort of side-effects were recorded during the period of intake; however, no side effects were observed.

[0038] Test Example 2 Comparison to Tricyclic Antidepressant

Comparison of the therapeutic effects on mood disorders between a tricyclic antidepressant and theanine was made in a group of 10 normofolatemic patients. In diagnosis, the patients were judged to be mild to severe according to the diagnostic criteria of DMS III R. The test was conducted in double blind, and the test period was 4 weeks. The 10 patients were divided into two even groups. One group was administered with the theanine-formulated tablet prepared in Example 3, and the other group was administered with a tricyclic antidepressant amitriptyline hydrochloride-formulated tablet in an amount of 50 mg per day. Each patient was administered with one tablet twice a day, at 10 am and 4 pm. The therapeutic effects were evaluated according to the Hamilton scale consisting of 31 items regarding assessment for depression. The assessment was made before the intake of each tablet and on Day 14 and Day 28 after the intake. In addition to the Hamilton scale, side effects were recorded in a questionnaire.

[0039] An average score of the Hamilton scale for each of the group of patients administered with the theanine-formulated tablet of Example 3 and the group administered with the amitriptyline hydrochloride-formulated tablet is shown in Figure 2. The average score in the Hamilton scale was significantly decreased from "29" before the intake to "23" on Day 14 or to "20" on Day 27 in the group administered with the theanine-formulated tablet in Example 3. In the group administered with the amitriptyline hydrochloride-formulated tablet, on the other hand, the score was decreased to "27" on Day 14 so that the effects were hardly recognized, but the score was then decreased to "20" on Day 27. As described above, it was confirmed that the effects of the theanine were exhibited more rapidly.

[0040] The records of side effects in each tested individual during the test period are as follows.

Theanine-Formulated Tablet of Example 3

Patient No.	Side Effects (Day 14)	Side Effects (Day 28)
A	None	None
B	None	None
C	None	None
D	None	None
E	None	None

Amitriptyline

Patient No.	Side Effects (Day 14)	Side Effects (Day 28)
F	Drowsiness	Drowsiness, Constipation
G	Dry Mouth	Dry Mouth
H	None	None
I	Constipation	Constipation
J	Palpitations, Constipation	Palpitations, Constipation

During the test period, no side effects were recognized in all the individuals administered with the theanine-formulated tablet of Example 3, but

side effects were recognized in 4 out of 5 individuals administered with that of the amitriptyline.

[0041] Test Example 3 Test for Treating Mood Disorders in Theanine-Formulated Foods

The test for treating mood disorders was conducted with the theanine-formulated candy of Example 4, the theanine-formulated blueberry beverage of Example 5 and the theanine-formulated grapefruit beverage of Example 6. The test was conducted for a group of 9 normofolatemic patients. In the diagnosis, the patients were judged to be mild to severe according to the diagnostic criteria of DMS III R. The test period was 4 weeks. The 9 patients were divided into groups, each consisting of 3 patients. Each patient was administered with the theanine-formulated candy of Example 4, the theanine-formulated blueberry beverage of Example 5, or the theanine-formulated grapefruit beverage of Example 6, twice a day, at 10 am and 4 pm. The therapeutic effects were evaluated according to the Hamilton depression scale consisting of 31 items regarding assessment for depression. The assessment was made before the intake of each composition and on Day 28 after the intake, during each of the days.

[0042] A score of the Hamilton scale for each patient during the period of intake is as follows:

Theanine-Formulated Candy of Example 4

Patient No.	Before Intake	Day 28
A	30	21
B	24	19
C	26	24

Theanine-Formulated Blueberry Beverage of Example 5

Patient No.	Before Intake	Day 28
D	38	30
E	22	20
F	35	33

Theanine-Formulated Grapefruit Beverage of Example 4

Patient No.	Before Intake	Day 28
D	38	30
E	22	20
F	35	33

The theanine-containing formulated foods also were recognized to have effects of treating mood disorders.

[0043]

[Effects of the Invention] As explained above, the inventive products have significant effects in suppressing depression, a mood disorder, so that it is very beneficial to use the inventive products when considered together with the aspects of its effects and safety.

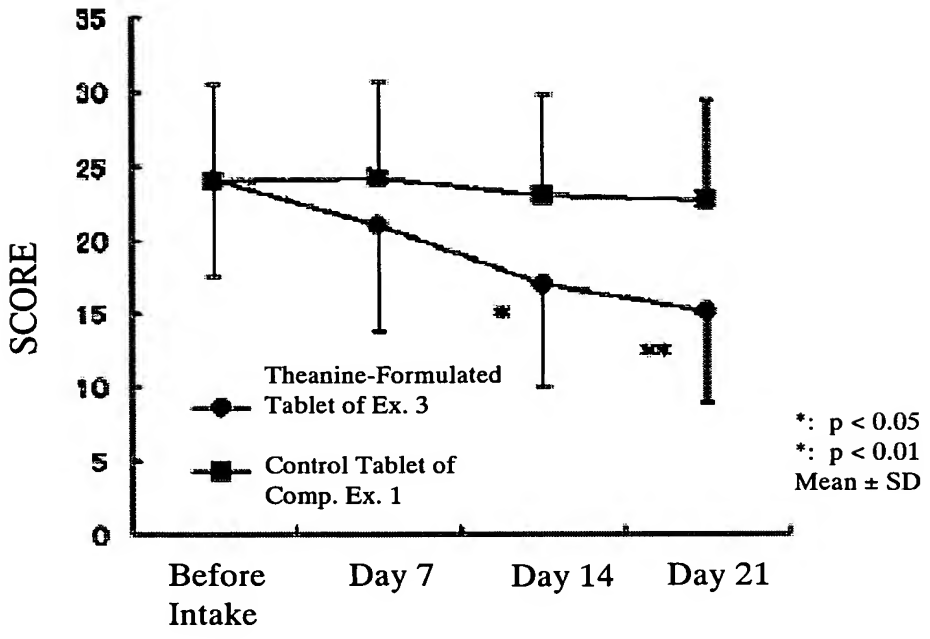
[0044]

[Brief Description of the Drawings]

[Figure 1] A graph showing a score of the Hamilton scale in the intake of the theanine-formulated tablet and the control tablet.

[Figure 2] A graph showing a score of the Hamilton scale in the intake of the theanine-formulated tablet and amitriptyline.

[Figure 1]



[Figure 2]